AUG 1 6 2001

K012156

5. 510 (k) Summary

Submitter of 510(k):	Wieland Edelmetalle GmbH & Co. Schwenninger Str. 13 D-75179 Pforzheim Germany Phone: +49-7231-3705-0
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Date of Summary:	2001-06-21
Trade name:	Imagine h.e.
Classification name:	Porcelain powder for clinical use
Product code:	EIH
C.D.R section:	872.6660
Classification:	Class II
Legally marketed equivalent device:	Duceragold
510(k) number:	K931808

510 (k) Summary

Device description

Imagine h.e. is a dental porcelain. It provides an easy to use and aesthetically pleasing dental restorative material to fabricate dental restorations. With its naturescent, brilliant shade effect, Imagine h.e. offers the dental technicians optimum conditions for achieving an exact reproduction of natural teeth.

Imagine h.e. is a dental glass-ceramic containing of leucite crystals (≤ 4 µm). Its firing temperature range lies between 820°C and 730°C

Originally developed for veneering dental alloys with high coefficient of thermal expansion [CTE (25-500°C): 16.1 –16.7 x $10^{-6}K^{-1}$] in the porcelain fused to metal technique, the range of indication of the Imagine h.e. has been extended to veneering of electroformed restorations made of AGC®-Galvanogold and of Imagine h.e. press-ceramic (Wieland Edelmetalle GmbH & Co.).

Imagine h.e. can be used for manufacturing inlays, partial crowns, crowns and bridges in the anterior as well as in the posterior region.

Imagine h.e. is market and clinically applicated in Europe, especially in Germany since March, 1999.

Imagine h.e. consists of the following porcelain powders:

Type of Powder	Shades
Paste opaque	A1; A2; A3; A3,5; A4; B1; B2; B3; B4; C1; C2; C3; C4; D2; D3; D4
Colour paste opaque	White, Violet, Orange, Brown
Opaque dentine	A1; A2; A3; A3,5; A4; B1; B2; B3; B4; C1; C2; C3; C4; D2; D3; D4
Dentine	A1; A2; A3; A3,5; A4; B1; B2; B3; B4; C1; C2; C3; C4; D2; D3; D4
Enamel Opal	SO57; SO58; SO59; SO60
Transparent	Clear; Opal; Blue; White; Yellow; Red; Orange; Grey
Shoulder porcelains margin	M1; M2; M3; M4; M5; M6; M7; M8; M9; M10
Dentine modifier	A; B; C; D; Orange; White
Mamelon modifier	Vanilla; Apricot; Sand; Lemon
Stains Colours	White; Orange; Olive; Blue; Brown; Black; Yellow; Violet; Chestnut; Grey
Glaze	GL
Correction	KD; KS
Gingiva	GV1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Gerhard Polzer
Director of Regulatory Affairs
Wieland Edelmetalle GMBH & Company
Schwenninger Strabe 13
Pforzheim,
GERMANY

Re: K012156
Trade/Device Name: Imagine H.E.
Regulation Number: 872.6660
Regulatory Class: II
Product Code: EIH
Dated: July 1, 2001
Received: July 11, 2001

Dear Mr. Polzer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012156

4. Statement of indication for use

Imagine h.e. is a dental porcelain that is used by dental technicians to fabricate porcelain fused to metal or to press-ceramic restorations. It is suitable for veneering alloys with a high coefficient of thermal expansion [$CTE_{(25 - 500°C)}$: 16.1–16.7 x $10^{-6}K^{-1}$], electroformed restorations, and heat-pressed ceramic frameworks made of the Imagine h.e. Press-Ceramic.

Imagine h.e. can be used for veneering of inlays, partial crowns, crowns, and bridges.

for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012156